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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No. *N/A*
Drohan *et al.*	Art Unit: 1631
Appl. No. 08/479,038	Examiner: Marschel, A.
Filed: June 7, 1995	Atty. Docket: 1327.0440006
For: **Supplemented and Unsupplemented Tissue Sealants, Methods of Their Production and Use**	

Ninth Supplemental Information Disclosure Statement Under 37 C.F.R. §1.56

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Disclosed herein are facts that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. § 1.56. These disclosures pertain to the inventorship of the invention. At the request of the American National Red Cross (ARC), the assignee of the present application, Sterne, Kessler, Goldstein & Fox P.L.L.C. has undertaken an analysis of the inventorship of the above-captioned application, and a petition to correct inventorship of the above-captioned application is being filed herewith. Summarized below are any results of this analysis that may be material.

In addition, listed on accompanying Form PTO-1449 are documents that are mentioned in the present Information Disclosure Statement, and that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Ninth Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Eighth Supplemental

Information Disclosure Statement, filed on June 24, 2003, in connection with the above-captioned application. Copies of the documents are provided.

1. Genzyme Corporation has asserted that Dr. John McPherson and Dr. Edward Nichols made an inventive contribution to the claimed embodiments in which fibrin sealants are supplemented with TGF-β. The ARC disagrees with this assertion. During a conference call with Genzyme, held on June 20, 2001, the undersigned attorney asked Maggie Kanter, counsel for Genzyme, for corroboration of any inventive contribution asserted by Genzyme scientists. This request was repeated in an October 23, 2001 letter from the undersigned to Ms. Kanter and during a November 26, 2001 conference call with her. To date, the undersigned attorney has received no such corroboration. At most, Genzyme alleges that Dr. McPherson and Dr. Nichols, while working at Genzyme, contributed to the enablement of fibrin sealant compositions supplemented with TGF-β, and to uses thereof, by allegedly determining that plasmin is needed to break down fibrin sealant compositions and release TGF-β. Ms. Kanter points to Example 10 in the above-captioned Application as evidence of Dr. McPherson's and Dr. Nichols's contribution.

After investigating Genzyme's allegations, the undersigned concluded that Drs. McPherson and Nichols did not contribute inventively to the invention claimed in the present application. This conclusion was based on the following facts:

(a) The above-captioned application is one in a series of applications. Supplementation of fibrin sealant compositions with TGF-β is described in the related U.S. Application No. 08/031,164 ["the '164 Application"] filed on March 12, 1993, prior to the collaboration between the ARC and Genzyme. Document AS75 is a copy of U.S. Application No. 08/328,552 ["the '552 Application"], which is a continuation of the '164 Application; thus, the

specification and figures of the '552 Application should be identical to the specification and figures of the '164 Application. A Material Transfer Agreement between the ARC and Genzyme became effective June 10, 1993 (Document AT75). TGF-β supplemented fibrin sealant compositions are disclosed in the '164 Application (see, e.g., Document AS75, page 18, lines 12-16; page 20, line 28; and page 41, lines 5-10).

(b) The present application does not claim the combination of plasmin and a fibrin sealant composition, nor does it claim any methods that recite the use of plasmin.

(c) Contrary to Genzyme's allegations, plasmin is not necessary for release of TGF-β from the fibrin sealant. Although plasmin enhanced the release of TGF-β from fibrin sealants in certain experiments conducted by Genzyme scientists, in which fibrin sealant compositions having unnecessarily high protein concentrations (60 mg/ml) were used, some TGF-β was released under the same experimental conditions in the absence of plasmin. Specifically, 2.5% of the 500 ng/ml preparation of TGF-β was released from a fibrin sealant composition having a protein concentration of 60 mg/ml (see Example 10 in the above-captioned application). The plasmin-mediated release of TGF-β was observed using high protein concentrations that were in the range that the ARC recommended for *hemostasis*, rather than for the release of supplements (Document AR76: Genzyme's report, section entitled "Release from Fibrin Glue"). When the protein concentration of the fibrin sealant composition was lowered to a range suitable for supplemented fibrin sealants designed to *release* the supplement, plasmin did not have a significant effect on the release of TGF-β (Document AR76: Genzyme's report dated June 29, 1995; *see* Table

FG092795 in section 3 of the report). As acknowledged by Genzyme in section 3 of the report, the lower protein concentrations were suggested to Genzyme by scientists at the ARC (Document AR76, section 3 of the report). The lower protein concentrations were conceived of by ARC scientists, and were previously described in Applicants' patent applications filed prior to the collaboration between the ARC and Genzyme (e.g., Document AS75, page 14, lines 17-20, and page 37, lines 9-11).

(d) Prior to the collaboration with Genzyme, the ARC scientists were aware that supplemented fibrin sealant compositions having high protein concentrations released the supplement more slowly than did fibrin sealant compositions having low protein concentrations. This finding is illustrated in the description of Figure 29 of the '164 application (see Document AS75, page 29, lines 24-26), filed prior to the collaboration with Genzyme. This example utilized a fibrin sealant composition that was supplemented with tetracycline. The rate of release of tetracycline from the fibrin sealant was dependent on the protein concentration of the fibrin sealant composition, and a lower protein concentration resulted in increased release of the supplement. Thus, it is clear that the ARC scientists knew to lower the protein concentration of fibrin sealant to obtain increased release of the supplement.

(e) Even if plasmin were required for release of TGF-β from the fibrin sealant, this requirement would have been inherently met during *in vivo* uses of the supplemented fibrin sealants. *In vivo* uses of the fibrin sealant compositions were described in the earlier-filed '164 Application, and would have resulted in contacting the supplemented fibrin sealant with blood. Plasmin, which is inherently contained within blood, breaks down the fibrin sealant *in vivo*. It

remains undisputed that the fibrin sealant is dissolved *in vivo* and that TGF-β is released during such dissolution. In situations in which plasmin may not be present in sufficient amounts (e.g., *in vitro*), TGF-β nonetheless could be released from the fibrin sealant without undue experimentation by using a fibrin sealant having a suitably low protein concentration, as described above.

In light of the foregoing facts, the discovery of plasmin-mediated release of TGF-β from fibrin sealants does not qualify Dr. McPherson or Dr. Nichols as a co-inventor of TGF-β-supplemented fibrin sealant or uses thereof.

On January 16, 2002, the undersigned attorney forwarded to Ms. Kanter excerpts of an Information Disclosure Statement (filed on January 9, 2002 in the related U.S. Application No. 08/486,048); the excerpts were substantially similar to paragraphs (1)(a) through (1)(e), above. The undersigned invited Ms. Kanter to forward to the undersigned any information that may be material to the inventorship issues discussed above. To date, the undersigned attorney has received no such information. In summary, the undersigned respectfully submits that Drs. McPherson and Nichols did not contribute inventively to any invention claimed in the above-captioned Application.

2. The undersigned understands that Dr. Manish Singh believes that, while employed as a scientist at the ARC, he contributed to the conception and/or enablement of fibrin sealant compositions supplemented with a supplement present in an amount above its solubility limit. Dr. Singh provided to the undersigned attorney a copy of a draft of a scientific paper on which Dr. Singh is a co-author (Document AS76). The paper describes methods of sustained release of supplements from fibrin sealant compositions, and to the best of the undersigned attorney's knowledge was authored in 1995.

The undersigned has a statement from Dr. Martin MacPhee, corroborated by copies of Dr. MacPhee's laboratory notebooks (see, *e.g.*, Document AT84, written prior to Dr. Singh's involvement with the ARC's fibrin sealant project), that fibrin sealant compositions containing a supplement in an amount above its solubility limit were invented without an inventive contribution by Dr. Singh. Therefore, the undersigned respectfully submits that Dr. Singh did not make an inventive contribution to any invention claimed in the present application.

3. The undersigned understands that Dr. Jeffrey Hollinger, formerly employed by the U.S. Army, believes that he contributed inventively to the conception and/or enablement of fibrin sealant compositions containing growth factors, including fibroblast growth factor. In response to our requests for corroboration of his alleged contributions, Dr. Hollinger produced documentation that, at most, corroborated only his contribution to fibrin sealant compositions containing demineralized bone matrix (DBM) and/or bone morphogenetic proteins (BMPs). Applicants have requested that the Examiner delete DBM and/or BMP embodiments from the claims through an Examiner's amendment, and the Examiner has indicated that he will do so. Therefore, because fibrin sealant compositions supplemented with DBM or BMPs will not be claimed in the above-captioned application, and because Dr. Hollinger has not provided corroboration of any contribution to the claimed invention, the undersigned has concluded that Dr. Hollinger should not be named as an inventor on this application.

4. The undersigned understands that Dr. Christian Haudenschild, an employee of the ARC, believes that he contributed inventively to the conception and/or enablement of fibrin sealant compositions supplemented with growth factors (e.g., FGF, IGF, EGF and VEGF), growth factor modulators (e.g., heparin), vasoconstrictors, vasodialators, steroids, anti-

inflammatories and cardiovascular drugs. Dr. Haudenschild also asserted that he contributed inventively to the enablement of fibrin sealant compositions supplemented with compounds useful for bone regeneration and/or repair. In addition, Dr. Haudenschild asserted that he contributed inventively to methods of sustained release of supplements from supplemented fibrin sealant compositions.

The undersigned attorney repeatedly asked Dr. Haudenschild to provide evidence to support his assertions. In response, Dr. Haudenschild provided to the undersigned a document dated January 25, 2002 and entitled "Chronological Description of Selected Records of Christian C. Haudenschild, M.D. Pertaining to American Red Cross' Fibrin Sealant Technology" (Document AT83), in which Dr. Haudenschild summarized events and documents that he believed may support his assertions. The Chronological Description was not accompanied by copies of the documents described therein. In addition, the entries in the Chronological Description did not provide the undersigned with sufficient detail (*e.g.*, experimental design, experimental results, and any improvements that Dr. Haudenschild may have made to the fibrin sealant technology as a result of the experiments described in the entry) to enable the undersigned to reach a conclusion as to Dr. Haudenschild's inventive contribution. Therefore, the undersigned sought a personal interview with Dr. Haudenschild during which the undersigned would have had the opportunity to view the documents described in the Chronological Description.

During a March 20, 2002 interview with the undersigned, Dr. Haudenschild provided to the undersigned a transcript of a lecture he gave in August 1993, in which he discussed the advantages of cardiovascular grafts coated with fibrin sealant (Document AR84). In addition, Dr. Haudenschild showed the undersigned his laboratory records, dating back to the beginning of his employment at the ARC. These records were in the form of a log book in which Dr. Haudenschild and others in the Experimental Pathology Department recorded information such

as the types of specimens, name of investigator, stain used on the slides and any special conditions for processing the specimens. Dr. Haudenschild stated that his contribution to the fibrin sealant technology was primarily made orally, while he was examining the slides, and that his comments, if recorded, would be found in the notebooks of the individuals to whom he spoke. Dr. Haudenschild did not provide the undersigned with, or direct the undersigned to, any such notebooks of others.

Dr. MacPhee, who, as mentioned above, is a named co-inventor on the present application, disputes that Dr. Haudenschild made an inventive contribution to any of the embodiments recited above. In support of his assertions, Dr. MacPhee has provided the undersigned with copies of his laboratory notebooks that predate Dr. Haudenschild's employment at the ARC (excerpts of the notebooks are enclosed as Document AS84).[1]

All of the claimed embodiments to which Dr. Haudenschild believes he contributed were (i) previously disclosed in Dr. MacPhee's laboratory notebooks (see Document AS84) and/or (ii) disclosed in related patent applications filed prior to Dr. Haudenschild's employment at the ARC. Although Dr. Haudenschild also asserted that he collaborated with one or more of the named co-inventors prior to his employment at the ARC, none of the documentation provided by Dr. Haudenschild was, in the opinion of the undersigned, sufficient to establish that Dr. Haudenschild should be named as a co-inventor on the above-captioned application. Based on the information currently available to the undersigned attorney, the undersigned attorney concludes that Dr. Haudenschild should not be named as a co-inventor on the above-captioned application.

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[1] The dates of the laboratory notebook entries have been redacted by the Applicants' representatives, as was additional information that is not believed to be material to the examination of the above-captioned application. The submission of these notebook entries should not be construed as an admission that these entries represent the earliest date of Applicants' conception of the embodiments discussed therein.

Listed below are the last known addresses of the scientists discussed above:

Dr. John M. McPherson, 72 Old Elm Way, Hopkinton, Massachusetts 01748.

Dr. Edward H. Nichols, 17 Nixon Road, Framingham, Massachusetts 01701.

Dr. Manish Singh, 10266 Wateridge Circle, Unit 225, San Diego, California 92121, temporarily residing at 3180 Sawtelle Blvd., #207, Los Angeles, California 90066.

Dr. Jeffrey Hollinger, Carnegie-Mellon University, 125D Smith Hall, 5000 Forbes Ave., Pittsburgh, Pennsylvania 15213.

Dr. Christian Haudenschild, c/o American Red Cross Holland Laboratory, 15601 Crabbs Branch Way, Rockville, Maryland 20855.

Dr. Martin J. MacPhee, c/o Clearant, Inc., 401 Professional Drive, Gaithersburg, Maryland 20879.

Drs. Hollinger was formerly employed by the U.S. Army, which is represented by Elizabeth Arwine, Esq. Ms. Arwine's address is: Office of the Staff Judge Advocate, U.S. Army Medical Research & Materiel Command, 504 Scott Street, Fort Detrick, Maryland 21702-5012. The U.S. Army is represented by George Metzenthin, Esq., Cahn & Samuels, L.L.P., Headquarters Building, 2000 P St. N.W., Washington, DC 20036.

Drs. McPherson and Nichols are employed by Genzyme Corporation, which is represented by Maggie Kanter, Esq., Senior Patent Counsel for Genzyme Corporation. Ms. Kanter's address is: Genzyme Corporation, One Kendall Square, Cambridge, MA 02139.

This Ninth Supplemental Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Attached is our PTO-2038 Credit Card Payment Form in the amount of $180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that these documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Eldora Ellison Floyd
Attorney for Applicants
Registration No. 39,967

Date: August 15, 2003

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

FORM PTO-1449 NINTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1327.0440006/JAG/EEF/M-G	APPLICATION NO. 08/479,038
	APPLICANT Drohan *et al.*	
	FILING DATE June 7, 1995	GROUP 1631

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR		
	AS	75	Copy of U.S. Application No. 08/328,552, filed on October 25, 1994.
	AT	75	Letter from Barry M. Datlof, Director of Patents and Licensing, American Red Cross on A Material Transfer Agreement, to James W. Burns, Genzyme Corporation, regarding a Material Transfer Agreement, with Material Transfer Agreement attached (dated May 26, 1993).

EXAMINER	DATE CONSIDERED

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	76	Genzyme Biotherapeutic Formulation & Delivery Research Report entitled "Research Report on TGF-β2 Formulated in Fibrin Glue" (dated June 29, 1995).
	AS	76	Singh, M., *et al.*, "Antibiotic Delivery from Fibrin Sealant," (1995) (unpublished manuscript)
	AT	76	Bowersox, J.C., Mission Plan of the Division of Military Trauma Research, Letterman Army Institute of Research, pp. 1-16 (October 1992).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	77	Hess, J.R., Draft of an animal use protocol (dated October 10, 1991).
	AS	77	Hess, J.R., Invention disclosure form for dry powder fibrin glue (October 1993).
	AT	77	Memorandum from John R. Hess to Dean Calcagni regarding fibrin glue proposal from Dr. Martin MacPhee, American Red Cross Holland Laboratory (dated May 18, 1994).

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	AR	78	Larson, M.J., *et al.*, "Efficacy of a Fibrin Hemostatic Bandage in Controlling Hemorrhage From Experimental Arterial Injuries," *Arch. Surg. 130*:420-422, American Medical Association (April 1995).
	AS	78	Hess, J., *et al.*, "Hemorrhage Control With a Dry Powdered Thrombin and Fibrinogen Bandage," *Nederl. Milit. Geneesk 49*:120-122, (August 1996)
	AT	78	Holcomb, J., *et al.*, "Efficacy of a Dry Fibrin Sealant Dressing for Hemorrhage Control After Ballistic Injury," *Arch. Surg. 133*:32-35, American Medical Association, (1998).

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	AR	79	Holcomb, J.B., *et al.*, "New technologies for hemorrhage control," *Curr. Opin. Crit. Care* 3:488-493, Rapid Science Publishers, (1997).
	AS	79	Holcomb, J.B., *et al.*, "Effect of Dry Fibrin Sealant Dressings versus Gauze Packing on Blood Loss in Grade V Liver Injuries in Resuscitates Swine," *J. Trauma: Injury, Infection, Critical Care* 46:49-57, Lippincott Williams & Wilkins, (1999).
	AT	79	Holcomb, J.B., *et al.*, "Dry Fibrin Sealant Dressings Reduce Blood Loss, Resuscitation Volume, and Improve Survival in Hypothermic Coagulopathic Swine with Grade V Liver Injuries," *J. Trauma: Injury, Infection, and Critical Care* 47:233-242, Lippincott Williams & Wilkins, Inc., (August 1999).

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	80	BEHRING product information regarding Beriplast® P, (undated).
	AS	80	Bowersox, J.C., Mission Statement for tissue adhesives for hemorrhage control, (October 1992).
	AT	80	Bowersox, J.C. *et al.*, "Fibrin Tissue Adhesive in Hemorrhage Control," Defense Research Science, pp. 1-19, unpublished, (dated February 25, 1992).

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	AR	81	Bowersox, J.C., Information paper regarding tissue adhesives for controlling hemorrhage, pp. 1-3,(dated February 28, 1992).
	AS	81	Memorandum from John Hess to Charles E. McQueen regarding MAJ Jackson's memo, (dated September 16, 1996).
	AT	81	Facsimile from Charles E. McQueen to John Hess regarding intellectual property rights for device conceived under CRDA, (dated September 10, 1996).

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	AR	82	Ingraham, F.C. and Bailey, O.T., "Clinical Use of Products of Human Plasma Fractionation," *J.A.M.A. 126*:680-685, The American Medical Association (1944).
	AS	82	Bowersox, J.C., Table of Contents from a set of notebooks (undated).
	AT	82	Bowersox, J.C., "Fibrin Tissue Adhesive Program, Priorities, Strategies, Plans," pp. 1-22, (unpublished report) (February 1994).

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	83	Bowersox, J.C., Appendix A to document AR74, "MEDCOM Requirements Addressed by Fibrin Tissue Adhesive Program," (February 1994).
	AS	83	Larson, M.J., *et al.*, "Preliminary Observations Using a Fibrin Adhesive Bandage to Control Hemorrhage From Experimental Arterial Injuries in Swine," pp. 1-15. (unpublished report) (undated).
	AT	83	Document entitled "Chronological Description of Selected Records of Christian C. Haudenschild, M.D. Pertaining to American Red Cross' Fibrin Sealant Technology," pp. 1-5, (dated January 25, 2002).

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 NINTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1327.0440006/JAG/EEF/M-G	APPLICATION NO. 08/479,038
	APPLICANT Drohan *et al.*	
	FILING DATE June 7, 1995	GROUP 1631

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	84	Haudenschild, C., "Vascular Grafts and Organoids" at the Chemical Society, Cells at Interfaces Symposium, Chicago (August 1993).
	AS	84	Copy of pages from Martin J. MacPhee's laboratory notebook, (undated).
	AT	84	Typed transcription of page, AT84, from Martin J. MacPhee's laboratory notebook, (undated).

EXAMINER	DATE CONSIDERED

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